

REMARKS

The Office Action of September 13, 2004, has been received and reviewed. The application is to be amended as set forth herein. All claim amendments are made without prejudice or disclaimer. Claims 1-7, 10-16, and 18-19 are pending. Claims 1-7, 10-16 and 18-19 stand rejected under 35 U.S.C. § 112, second paragraph, as assertedly being indefinite. Claims 1-5, and 11-14 stand rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by Bell *et al.* Claims 18-19 stand rejected under 35 U.S.C. § 103 as assertedly being unpatentable over Bell *et al.* Claims 6-7 stand rejected under 35 U.S.C. § 103 as assertedly being unpatentable over Bell *et al.* in view of Schreuder *et al.* Claims 15-16 stand rejected under 35 U.S.C. § 103 as assertedly being unpatentable over Bell *et al.* in view of Prusiner *et al.*

Amendment of the Specification:

A number of objections to the specification are noted in the Office Action. The applicants have amended the application as suggested by the Examiner to include the Cross-Reference to Related Applications. In addition, the applicants have corrected the typographical errors noted on pages 2, 7, 8, 19 and 33 of the specification.

In light of the amendments, reconsideration and withdrawal of the objection are respectfully requested.

Support for Amendments:

Support for the amendments to the specification can be found throughout the specification and claims as filed. In particular, the amendments to the specification correct obvious typographical errors, for example, the amendment of page 8, lines 27-28, merely grammatically fills in the sentence, support for this amendment can be found, for example, on page 7, lines 20-26 of the specification. Reconsideration and withdrawal of the rejection are respectfully requested.

Support for the claim amendments can be found throughout the specification and claims as filed. For example, support for the amendment of claim 1 can be found in claim 1 and page 24, line 19 to page 25, line 11 of the specification. Support for claims 18 and 19 can be found throughout the specification, for example, on page 20, lines 14-22. Claim 10 has been amended

as suggested by the Examiner.

Rejections under 35 U.S.C. § 112, second paragraph:

Claims 1-7, 10-16, and 18-19 are pending. Claims 1-7, 10-16 and 18-19 stand rejected under 35 U.S.C. § 112, second paragraph, as assertedly being indefinite. Specifically, claims 1 and 10 recited "derived" from a mammal, which was believed to be indefinite. The claims have been amended as suggested by the Examiner to recite "obtained" from a mammal. Claims 2-7, 11-16, 18 and 19 stand rejected as depending from claims 1 and 10. In view of the amendment, reconsideration and withdrawal of the rejection are respectfully requested.

Claim 2 stands rejected as assertedly failing to impose new criticality into the method. Claim 2 has been amended, and reconsideration and withdrawal of the rejection are thus respectfully requested.

Claim 14 stands rejected as the phrase "or functional equivalents thereof" is asserted to be unclear. Functional equivalents of the sequences are known in the art. However, to expedite prosecution of the application, claim 14 has been amended to remove the terminology. Reconsideration and withdrawal of the rejection are respectfully requested.

Claim 18 stands rejected as the phrase "part comprising a means for performing" the method is asserted to be indefinite. Although applicants respectfully disagree, *see* 35 U.S.C. § 112, paragraph six, in order to expedite prosecution of the application, the applicants have amended the claim to recite specific means for performing the method. Reconsideration and withdrawal of the rejection are thus respectfully requested.

Claim 19 stands rejected as the term "design" is asserted to be indefinite. The applicants have amended claim 19 to rephrase the rejected term and to substitute the alternative phrasing for mass-screening. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejections under 35 U.S.C. § 102(b):

Claims 1-5, and 11-14 stand rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by Bell *et al.* The applicants respectfully point out that the list of rejected claims and the discussion of the rejection do not appear to coincide. The applicants are of the opinion that the rejection is more properly drawn to claims 1, 2 and 10. Regardless, claim 1 has been

amended to recite "without pre-treating said at least one sample with formic acid, and testing said at least one sample for the presence or absence of an aberrant prion protein," which is not disclosed in Bell *et al.* For example, see Table 1 of Bell *et al.* where Centre 1 and 5 pre-treat the sample with formic acid before treatment with guanidine thiocyanate. *See also*, Bell *et al.* at page 28, second column, describing the use of pre-treatment with formic acid and that the "omission of such a step produced unacceptable levels of background staining." Furthermore, *see*, page 29, second column, wherein the authors state that "formic acid was an essential pre-treatment" and question the use of guanidine thiocyanate. Finally, *see* page 33, second column, where the authors state that "[p]re-treatment with formic acid is regarded as mandatory." Hence, Bell *et al.* not only does not teach the absence of a pre-treatment with formic acid, the authors specifically and repeatedly teach away from such a method, *e.g.*, "[p]re-treatment with formic acid is ... mandatory." *Id.*

Since Bell *et al.* does not disclose each element of the claimed method, the reference cannot anticipate the claims. Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection under 35 U.S.C. § 103:

Claims 18-19 stand rejected under 35 U.S.C. § 103 as assertedly being unpatentable over Bell *et al.* Claims 6-7 stand rejected under 35 U.S.C. § 103 as assertedly being unpatentable over Bell *et al.* in view of Schreuder *et al.* Claims 15-16 stand rejected under 35 U.S.C. § 103 as assertedly being unpatentable over Bell *et al.* in view of Prusiner *et al.*


As discussed herein, Bell *et al.* does not teach or suggest all of the claim elements. In addition, Bell *et al.* teaches away from the claimed method, for example, stating that "formic acid was an essential pre-treatment." *Id.* at 29. Therefore, Bell *et al.* cannot be properly combined with either Schreuder *et al.* and/or Prusiner *et al.* Moreover, neither Schreuder *et al.* nor Prusiner *et al.* teach or suggest the missing elements. Thus, Bell *et al.* in combination with Schreuder *et al.* and/or Prusiner *et al.* do not teach all of the claim elements and Bell *et al.* teaches away from the claimed method, making it improper to combine Bell *et al.* with either Schreuder *et al.* or Prusiner *et al.*


Reconsideration and withdrawal of the rejection are respectfully requested.

CONCLUSION

Should questions remain after entry of the amendments and consideration of the remarks herein that may be addressed by a telephonic interview, the Office is invited to contact the applicants' representative at the number provided herein.

Respectfully submitted,

 Reg No
33,041

 G. Scott Dorland, Ph.D.
Registration No. 51,622
Attorney for Applicants
TRASKBRITT, P.C.
P.O. Box 2550
Salt Lake City, Utah 84110-2550
Telephone: 801-532-1922

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